

Initial Prior Authorization Nutritional Supplements–Renal Dysfunction Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name
Kate Farms Renal Support 1.8
Magnacal Renal
Nepro
Nepro Carb
Nepro Carb Steady
Novasource Renal
Nutramine
Nutrirenal
Pro-Stat RC
Re/Gen
Re/Gen Prote
Renalcal
Renastart
Renastep
Suplena

Reference number(s)
339-A

Indications

FDA-approved Indications

N/A

Coverage Criteria

Authorization may be granted for requested product when ALL of the following criteria are met:

- The product is medically necessary due to a diagnosis of renal dysfunction
- The patient meets ONE of the following:
 - The product is medically necessary to avoid serious malnutrition
 - Lack of this product would result in serious disability or death

Duration of Approval (DOA)

- 339-A: DOA: Lifetime

References

1. Mass. Gen. Laws Ch. 176B Section 4K, Coverage for nonprescription enteral formulas for home use. Available at: <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176B/Section4K>.
2. California Code of Regulations [CCR], Title 22, Section 51313.3. Available at: <https://files.medical.ca.gov/pubsdoco/Publications/masters-MTP/Part2/enteral.pdf>.
3. RI Gen L § 27-41-74 (2021) Enteral nutrition products. Available at: <https://law.justia.com/codes/rhode-island/2021/title-27/chapter-27-41/section-27-41-74/>.

Document History

Written by: UM Development (NB)

Date Written: 01/2008

Revised: UM Development (SE) 04/2009; 02/2010, 06/2012, (SE) 04/2013, 08/2013, 01/2014, 04/2014, 08/2014, 12/2014, 03/2015 (SF) 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 12/2018, 12/2019, 12/2020; (RP) 06/2021 (added products to target list); (RZ) 12/2021 (no clinical changes), 01/2022 (added products to target list), (VLS) 12/2022 (no clinical changes), 12/2023 (no clinical changes), 12/2024 (no clinical changes)

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Reference number(s)
339-A

Reviewed: CDPR: 01/2008; Medical Affairs (WLF) 04/2009, (DNC) 06/2012, (KP) 04/2013, (LMS) 08/2013, (KP) 01/2014, (SES) 04/2014, (DHR) 08/2014, (DNC) 12/2014, (SES) 04/2015 (DNC) 06/2015, (LCB) 09/2015, (JG) 12/2016, (LMS) 12/2017, (EPA) 12/2018, (CHART) 01/09/2020, 01/14/2021, 07/08/2021, 12/30/2021, 02/10/2022, 12/29/2022, 12/21/2023, 01/16/2025

External Review: 08/2008, 08/2012

Guidelines for Approval

Set 1 – 2

Duration of Approval: Lifetime

Set 1

Yes to question(s)	No to question(s)
1, 2	None

Set 2

Yes to question(s)	No to question(s)
1, 3	2

CRITERIA FOR APPROVAL

1	Is this product medically necessary due to a diagnosis of renal dysfunction? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is this product medically necessary to avoid serious malnutrition? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Would lack of this product result in serious disability or death? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is when you have a medical need for it due to poor kidney function. Your plan does not cover this drug for your

			<p>health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Approve, LIFETIME	Go to 3	
3.	Approve, LIFETIME	Deny	<p>Your plan only covers this drug when you have a medical need for it to avoid serious malnutrition or if lack of the product would result in serious disability or death. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Malnutrition/Disability/Death]</p>